

(3) *Nonlactating cattle*—(i) *Amount*. Five milliliters intramuscularly as a single injection.

(ii) *Indications*. For its abortifacient effect in nonlactating cattle.

(iii) *Limitations*. For intramuscular use only, during first 100 days of gestation. Cattle that abort will abort within 35 days after injection. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) *Lactating dairy cattle*—(i) *Amount*. Five milliliters intramuscularly as a single injection.

(ii) *Indications*. For treatment of unobserved (silent) estrus in lactating dairy cattle that have a corpus luteum.

(iii) *Limitations*. Breed cattle as they are detected in estrus. If estrus has not been observed by 80 hours after injection, breed at 80 hours. If cattle return to estrus breed at the usual time relative to estrus. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(5) *Swine*—(i) *Amount*. 2 milliliters (equivalent to 10 milligrams of dinoprost).

(ii) *Indications*. For parturition induction in swine when injected within 3 days of normal predicted farrowing.

(iii) *Limitations*. For use in swine as follows: Inject a dose of 2 milliliters intramuscularly within 3 days of predicted farrowing. The response to treatment varies by individual animals with a mean interval from administration to parturition of approximately 30 hours. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[41 FR 4818, Feb. 2, 1976, as amended at 46 FR 13214, Feb. 20, 1981; 46 FR 39127, July 31, 1981; 48 FR 6331, Feb. 11, 1983; 48 FR 46023, Oct. 11, 1983; 49 FR 4373, Feb. 6, 1984]

§ 522.723 Diprenorphine hydrochloride injection.

(a) *Chemical name*. N-(Cyclopropylmethyl)-6,7,8,14-tetrahydro-7- α -(1-hydroxy - 1 - methylethyl) - 6,14 - endoethanonoripavine hydrochloride.

(b) *Specifications*. Each milliliter of diprenorphine hydrochloride injection, veterinary, contains 2 mg of diprenorphine hydrochloride in sterile aqueous solution.

(c) *Sponsors*. See No. 010042 in § 510.600(c) of this chapter.

(d) *Conditions of use*. (1) The drug is used for reversing the effects of etorphine hydrochloride injection, veterinary, the use of which is provided for in § 522.883, in wild and exotic animals.

(2) It is administered intramuscularly or intravenously at a suitable dosage level depending upon the species.

(3) For use in wild or exotic animals only. Do not use in domestic food-producing animals. Do not use 30 days before, or during, the hunting season in free-ranging wild animals that might be used for food.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian. Distribution is restricted to veterinarians engaged in zoo and exotic animal practice, wildlife management programs and researchers.

[40 FR 13858, Mar. 27, 1975, as amended at 48 FR 16241, Apr. 15, 1983; 60 FR 39847, Aug. 4, 1995]

§ 522.740 Disophenol sodium injection.

(a) *Chemical name*. Sodium 2,6-diiodo-4-nitrophenoxide.

(b) *Specifications*. The drug is sterile and contains the equivalent of 0.9 or 4.5 percent disophenol in polyethylene glycol 400 and distilled water.

(c) *Sponsor*. See No. 000859 in § 510.600(c) of this chapter.

(d) *Conditions of use*. (1) The drug is used for the treatment of both dogs infested with hookworms (including *Ancylostoma caninum*, *A. braziliense* and *Uncinaria stenocephala*) and cats infested with the hookworm *A. tubaeforme*.

(2) It is administered subcutaneously at a dosage level equivalent to 4.5 milligrams of disophenol per pound of body weight. A second treatment may be indicated 21 days after the initial treatment.

(3) Do not repeat treatment in less than 21 days.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(5) Use for the treatment of dogs infested with hookworms (including *Ancylostoma caninum*, *A. braziliense* and *Uncinaria stenocephala*) is NAS/NRC reviewed and deemed effective. Applications for these uses need not include

effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

[40 FR 13858, Mar. 27, 1975, as amended at 41 FR 43400, Oct. 1, 1976; 42 FR 41855, Aug. 19, 1977; 45 FR 43402, June 27, 1980; 47 FR 14150, Apr. 2, 1982]

§ 522.775 Doxapram hydrochloride injection.

(a) *Specifications.* The drug is a sterile aqueous solution containing 20 milligrams doxapram hydrochloride per milliliter.

(b) *Sponsor.* See No. 000031 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) Administer to dogs, cats, and horses to stimulate respiration during and after general anesthesia; to speed awakening and return of reflexes after anesthesia. Administer to neonate dogs and cats to initiate respiration following dystocia or caesarean section; to stimulate respiration following dystocia or caesarean section.

(2) For intravenous use in dogs and cats at a dose of 2½ to 5 milligrams of doxapram hydrochloride per pound of body weight in barbiturate anesthesia, 0.5 mg per lb. in gas anesthesia; for intravenous use in horses at 0.25 mg per lb. of body weight in barbiturate anesthesia, 0.2 mg per lb. in inhalation anesthesia, 0.25 mg per lb. with chloral hydrate with or without magnesium sulfate; for subcutaneous, sublingual, or umbilical vein administration in neonate puppies at a dose rate of 1 to 5 mg; for subcutaneous or sublingual use in neonate kittens at 1 to 2 mg. Dosage may be repeated in 15 to 20 minutes if necessary.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 17838, Apr. 23, 1975]

§ 522.784 Doxylamine succinate injection.

(a) *Specifications.* Each milliliter of the drug contains 11.36 mg of doxylamine succinate.

(b) *Sponsor.* See No. 011716 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in conditions in which antihistaminic therapy may be expected to al-

leviate some signs of disease in horses, dogs, and cats.¹

(2) It is administered to horses at a dosage level of 25 mg per hundred pounds of body weight. It is administered to dogs and cats at a dosage level of 0.5 to 1 mg per pound of body weight. Doses may be repeated at 8 to 12 hours, if necessary, to produce desired effect. Intravenous route is not recommended for dogs and cats and should be injected slowly in horses. Intramuscular and subcutaneous administration should be by divided injection sites.¹

(3) Not for use in horses intended for food.¹

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[40 FR 13858, Mar. 27, 1975, as amended at 42 FR 60140, Nov. 25, 1977; 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996]

§ 522.800 Droperidol and fentanyl citrate injection.

(a) *Specifications.* Droperidol and fentanyl citrate injection is a sterile solution containing 20 milligrams of droperidol and 0.4 milligram of fentanyl citrate per cubic centimeter.

(b) *Sponsor.* See No. 000045 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in dogs as an analgesic and tranquilizer and for general anesthesia.

(2) It is administered as follows:

(i) For analgesia and tranquilization administer according to response desired, as follows:

(a) Intramuscularly at the rate of 1 cubic centimeter per 15 to 20 pounds of body weight in conjunction with atropine sulfate administered at the rate of 0.02 milligram per pound of body weight, or

(b) Intravenously at the rate of 1 cubic centimeter per 25 to 60 pounds of body weight in conjunction with atropine sulfate administered at the rate of 0.02 milligram per pound of body weight.

(ii) For general anesthesia administer according to response desired, as follows:

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter.